UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

In re:	PROMESA Title III
THE FINANCIAL OVERSIGHT AND MANAGEMENT BOARD FOR PUERTO RICO,	
as representative of	No. 17 BK 3283-LTS
THE COMMONWEALTH OF PUERTO RICO, et al.,	(Jointly Administered)
Debtors.[1]	

NOTICE OF CORRESPONDENCE RECEIVED BY THE COURT

The Court has received and reviewed the attached correspondence, described below, from interested persons in the above-captioned cases. Although the Court cannot respond individually to all of those who have expressed their thoughts or concerns, the Court is deeply mindful of the impact of the fiscal crisis on lives, institutions, and expectations, and of the importance of the issues that are raised in these unprecedented cases.

1. Letter dated December 18, 2020 from the Independent Local Community Pharmacies.

Dated: December 21, 2020

[1] The Debtors in these title III cases, along with each Debtor's respective title III case number listed as a bankruptcy case number due to software limitations and the last four (4) digits of each Debtor's federal tax identification number, as applicable, are the (i) Commonwealth of Puerto Rico (the "Commonwealth") (Bankruptcy Case No. 17-BK-3283 (LTS)) (Last Four Digits of Federal Tax ID: 3481), (ii) Employees Retirement System of the Government of the Commonwealth of Puerto Rico ("ERS") (Bankruptcy Case No. 17-BK-3566 (LTS)) (Last Four Digits of Federal Tax ID: 9686), (iii) Puerto Rico Highways and Transportation Authority ("HTA") (Bankruptcy Case No. 17-BK-3567 (LTS)) (Last Four Digits of Federal Tax ID: 3808), (iv) Puerto Rico Sales Tax Financing Corporation ("COFINA") (Bankruptcy Case No. 17-BK-3284 (LTS)) (Last Four Digits of Federal Tax ID: 8474); (v) Puerto Rico Electric Power Authority ("PREPA") (Bankruptcy Case No. 17-BK-4780) (Last Four Digits of Federal Tax ID: 3747); and (vi) Puerto Rico Public Buildings Authority ("PBA") (Bankruptcy Case No. 19-BK-5233-LTS) (Last Four Digits of Federal Tax ID: 3801).

December18, 2020

ADVANCE BY EMAIL TO: swaindprcorresp@nysd.uscourts.gov

BY CERTIFIED MAIL TO:

7020-1290-0002-3027-5415

The Honorable Laura Taylor Swain
United States District Judge
José V. Toledo Federal Building & US Courthouse
300 Recinto Sur Street
San Juan, PR 00901

In Re: **Adv. Proc. No. 20-00080 LTS: Independent Local Community Pharmacies' Respectful Submittal for the Consideration of Judge Taylor Swain of Study by Advantage Business Consulting on Lack of Fiscal Impact and Potential Economic Benefit of Public Law No. 82 of 2019 Regulating Pharmacy Benefit Managers (PBMs) and Pharmacy Benefit Administrators (PBAs).**

Dear Judge Taylor Swain,

The undersigned group of locally owned and operated independent community pharmacies, we are an important part of local small business pharmacies, in the same way, wholly owned and operated by families, individuals, and small businesses in Puerto Rico. As independent small businesses, our independent community pharmacies cannot leverage on Pharmacy Benefit Administrators (PBAs) and Pharmacy Benefit Managers (PBMs) the influence that big chain pharmacies, such as CVS or Walgreens can. PBMs and PBAs are middlemen entities that force unfair practices upon the small pharmacies and small businesses. Because these are big corporate entities that control distribution and wholesale of drugs and medications to small retail entities, very often the small pharmacies at the end of the chain end up receiving less payment or discount from PBMs and PBAs than the floor price they sell to the patient-consumer. The result of these unfair practices is that many times they force small pharmacies to close operations. Thus, independent community pharmacies are an easy prey to PBAs and PMBs that can result, and do result, in unjustifiably high prices for medications to the public.

Is for this reason that our group of independent, locally owned, and operated Community Pharmacies support the full enactment of Public Law No. 82 of 2019, to regulate PBMs and PBAs in Puerto Rico and reject the position taken by the Financial Oversight and Management Board for Puerto Rico ("FOMB"), to oppose the implementation of Law No. 82. Among other reasons, the

FOMB based its initial opposition to Law No. 82 on an alleged lack of formal estimates of the economic impact of Law No. 82 by the Government of Puerto Rico, a matter that is submitted for the Court's consideration, and an alleged failure by the Government of Puerto Rico to provide a legal analysis as to why Act No. 82 is not pre-empted by ~~a~~ federal statute. *See,* **Exhibit 1** to this Letter (FOMB Letter of November 15, 2019).

This latter issue on pre-emption raised by the FOMB, was very recently resolved by the United Supreme Court in Rutledge v. Pharmaceutical Care Management Association 592 U.S. ____ (2020), decided on December 10, 2020, wherein the Supreme Court, in an unanimous Opinion issued by Justice Sotomayor, firmly rejected the argument by a trade association for PBMs that the federal Employee Retirement Income Security Act ("ERISA"), pre-empts any aspect of an Arkansas statute that requires: (i) PBMs to "tether" their reimbursement rates to the acquisition costs pharmacies pay, by updating price schedules whenever wholesale drug prices increase; (ii) specifies an appeal process PBMs must provide when a pharmacy contends that the reimbursement level for a drug is below the pharmacy's cost of buying the drug; and (iii) allows a pharmacy to decline to sell a drug if the PBM's reimbursement price is lower than the pharmacy's cost. *See*, **Exhibit 2** of this Letter (Supreme Court's Opinion).

Law No. 82 regulates similar practices of PBMs and PBAs, as the Arkansas statute does. Therefore, given the Supreme Court Opinion, the FOMB's request for a legal analysis on pre-emption is moot and no longer a valid point for opposing implementation of Law No. 82.

The remaining issues raised by the Government of Puerto Rico in its Adversary Complaint (Adv. Proc. No. 20-00080 (LTS)), to oppose the position of the FOMB in the full implementation of Law No. 82, rest to be resolved by your Court, upon addressing the controversies of fact and law regarding the alleged failure by the Commonwealth of Puerto Rico to provide to the FOMB "formal estimates" of the economic impact of Law No. 82. Given that our group of independent locally owned and operated Community Pharmacies is not a party to the case, we respectfully submit for the consideration of the Court the Independent Analysis prepared by *Advantage Business Consulting*, a well-known economist Mr. Juan Lara, Ph.D firm, which was submitted to the Honorable Governor Wanda Vázquez Garced, through Edna I. Díaz de Jesús, BHE, MPA, Patient's Advocate, on February 19, 2020, entitled "*Lack of Fiscal Impact and Potential Economic Benefit of Public Law No. 82 of 2019 Regulating Pharmacy Benefit Managers (PBMs) and Pharmacy Benefit Administrators (PBAs)*". *See*, **Exhibit 3** to this Letter.

It is the conclusion of Advantage Business Consulting that Law No. 82 has: (i) no fiscal impact that could render it objectionable in light of the Fiscal Plan and Budget of the Commonwealth of Puerto Rico; (ii) that a positive fiscal impact may be expected from Law No. 82 due to the collection of licensing and audit fees, and, mostly, from the potential savings to the government health plan (the GHP) as a client of PBMs; and (iii) Law No. 82 embodies measures to promote the healthy management and oversight of government funds, which is in line with the objectives and directives of the FOMB.

We respectfully submit this correspondence and the exhibits attached hereto for your consideration, hoping that these may be of assistance by illustrating the Court about the view that independent locally owned and operated Community Pharmacies in Puerto Rico hold in supporting the implementation of Law No. 82, which provides a framework of regulation to help balance the inequities that we, locally owned and operated Community Pharmacies, face with PBMs and PBAs, mostly due to the lack of transparency. These business practices have led to inflation in the acquisitions cost and materially diminish the availability and timely access of drugs and medications for the indigent population covered by the Government Health Insurance Plan; likewise, properly, and solely served by the Community Pharmacies established around the Island.

We thank you in advance for your due consideration to our correspondence.

Respectfully,

Pharmacy: FARMACIA EL COMBATE INC by: _____
Dr. David A. Jiménez Martínez

Pharmacy: PHARMAMED PHARMACY INC by: _____
Mr. Luis Virella Nieves

Pharmacy: ALLMED PHARMACY LLC by: _____
Mr. Adalberto Llera Rolón

Pharmacy: FARMACIA EL EDEN by: _____
Lcdo. Ricardo E. Frontera Benvenutti

FINANCIAL OVERSIGHT AND MANAGEMENT BOARD FOR PUERTO RICO

BY ELECTRONIC MAIL

November 15, 2019

The Honorable Wanda Vázquez Garced
Governor of Puerto Rico
La Fortaleza

Dear Governor Vázquez Garced:

We have reviewed, and write to you in connection with, Act 82-2019, Act 90-2019, and Act 138-2019, pursuant to Section 204(a) of PROMESA.

Act 82-2019

Act 82-2019 creates a "Regulatory Law for Pharmacy Benefits and Services Administrators" and establishes an "Office of the Regulatory Commissioner of Pharmacy Benefits and Services Administrators" in the Puerto Rico Department of Health ("PRDH") to further regulate Pharmacy Benefit Managers ("PBMs"), Pharmacy Benefit Administrators ("PBAs") and any similar entity that contracts services from pharmacies in Puerto Rico, among other purposes.

While Act 82-2019 was signed into law on July 30, 2019, the Oversight Board has not received the formal cost estimate and certification of compliance or noncompliance as required by PROMESA Section 204(a)(2).

Moreover, the Oversight Board believes that there is possible federal preemption of the subject matter covered by Act 82-2019 under the statutory provisions of Title 42 of the U.S. Code and related Code of Federal Regulations.

The Oversight Board looks forward to receiving the required cost estimate and certification of compliance or noncompliance for Act 82-2019 and requests that you provide an explanation as to why Act 82-2019 is not preempted.

Act 90-2019

Act 90-2019, among other matters, amends Article 19.150 of Act 77-1957, known as the "Insurance Code of Puerto Rico" ("Act 77-1957"), to prohibit a Medicare Advantage health

service organization or its representative to agree with a service provider to pay a rate lower than the one established for that year by the Centers for Medicare and Medicaid Services ("CMS") for the services provided as Medicare Advantage. In addition, Act 90-2019 prohibits all such health service organizations or their representatives, including PBMs and PBAs, from cancelling or terminating a contract duly established with a provider or health professional without just cause.

The Oversight Board received Act 90-2019 along with the corresponding compliance certification required by PROMESA Section 204(a) (the "Compliance Certification"), past the statutorily mandated 7 business-days period. As set forth more fully below, this is not in compliance with PROMESA Section 204(a) with respect to Act 90-2019.

Act 138-2019

Act 138-2019 adds Article 31.031 and Article 31.032 to Chapter 31 of Act 77-1957 to establish that a health service organization cannot deny an application from a doctor, hospital, primary service center… or any other person authorized in Puerto Rico to provide health care services to become a provider of the same when they meet all the necessary requirements…; as well as to establish that no health insurance organization, insurer… or any other medical plan can include in any contract or stipulate with a health provider a unilateral cancelation of the contract.

The Oversight Board received Act 138-2019 and its corresponding Compliance Certification, required by PROMESA Section 204(a), past the statutorily mandated 7 business-days period.

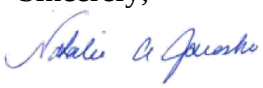
Having reviewed Act 90-2019, Act 138-2019 and their respective Compliance Certifications, the Oversight Board concludes that the Compliance Certification for both statutes fail to provide the formal estimate of the fiscal impact as required under paragraph (2)(A) of PROMESA Section 204(a). Further, the Oversight Board is also of the opinion that the subject matters covered by Act 90-2019 and Act 138-2019 are preempted by the statutory provisions of Title 42 of the U.S. Code and related Code of Federal Regulations.

In view of the foregoing, we hereby respectfully request that a formal estimate of the impact each Act will have on expenditures and revenues, including the impact on the government's medical health insurance plan ("Vital"), as required by PROMESA Section 204(a)(2)(A). Further, we ask for an analysis of Acts 82-2019, 90-2019 and 138-2019 in relation to the corresponding federal statutes to ascertain there are no conflicting provisions that may jeopardize the grant of federal funds to the PRDH.

Should the Oversight Board determine that you have failed to comply with our directive under Section 204(a)(4)(A), or that a law impairs or defeats the purposes of PROMESA, as determined by the Oversight Board, we reserve the right to take such actions as we consider necessary, consistent with Section 204(a)(5), including preventing the enforcement or application of Act 82-2019, Act 90-2019 and Act 138-2019.

Please submit the required information by no later than November 22, 2019.

Sincerely,



Natalie A. Jaresko

CC: Mr. Elí Díaz Atienza
Mr. Omar J. Marrero Díaz

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

RUTLEDGE, ATTORNEY GENERAL OF ARKANSAS *v.* PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 18–540. Argued October 6, 2020—Decided December 10, 2020

Pharmacy benefit managers (PBMs) act as intermediaries between pharmacies and prescription-drug plans. In that role, they reimburse pharmacies for the cost of drugs covered by prescription-drug plans. To determine the reimbursement rate for each drug, PBMs develop and administer maximum allowable cost (MAC) lists. In 2015, Arkansas passed Act 900, which effectively requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than the pharmacy's wholesale cost. To accomplish this result, Act 900 requires PBMs to timely update their MAC lists when drug wholesale prices increase, Ark. Code Ann. §17–92–507(c)(2), and to provide pharmacies an administrative appeal procedure to challenge MAC reimbursement rates, §17–92–507(c)(4)(A)(i)(*b*). Act 900 also permits Arkansas pharmacies to refuse to sell a drug if the reimbursement rate is lower than its acquisition cost. §17–92–507(e). Respondent Pharmaceutical Care Management Association (PCMA), which represents the 11 largest PBMs in the country, sued, alleging, as relevant here, that Act 900 is preempted by the Employee Retirement Income Security Act of 1974 (ERISA). Following Circuit precedent in a case involving a similar Iowa statute, the District Court held that ERISA pre-empts Act 900. The Eighth Circuit affirmed.

Held: Arkansas' Act 900 is not pre-empted by ERISA. Pp. 4–10.

(a) ERISA pre-empts state laws that "relate to" a covered employee benefit plan. 29 U. S. C. §1144(a). "[A] state law relates to an ERISA plan if it has a connection with or reference to such a plan." *Egelhoff*

v. *Egelhoff,* 532 U. S. 141, 147. Act 900 has neither of those impermissible relationships. Pp. 4–7.

(1) Act 900 does not have an impermissible connection with an ERISA plan. To determine whether such a connection exists, this Court asks whether the state law "governs a central matter of plan administration or interferes with nationally uniform plan administration." *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U. S. 312, 320. State rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not pre-empted by ERISA. See *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.,* 514 U. S. 645, 668. Like the law at issue in *Travelers*, Act 900 is merely a form of cost regulation that does not dictate plan choices. Pp. 4–6.

(2) Act 900 also does not "refer to" ERISA. It does not " 'ac[t] immediately and exclusively upon ERISA plans,' " and " 'the existence of ERISA plans is [not] essential to the law's operation.' " *Gobeille*, 577 U. S., at 319–320. Act 900 affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract, and Act 900 regulates PBMs whether or not the plans they service fall within ERISA's coverage. ERISA plans are therefore also not essential to Act 900's operation. Pp. 6–7.

(b) PCMA's contention that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration is unconvincing. First, its claim that Act 900 affects plan design by mandating a particular pricing methodology for pharmacy benefits is simply a long way of saying that Act 900 regulates reimbursement rates. Second, Act 900's appeal procedure does not govern central matters of plan administration simply because it requires administrators to comply with a particular process and may require a plan to reprocess how much it owes a PBM. Taken to its logical endpoint, PCMA's argument would pre-empt any suits under state law that could affect the price or provision of benefits, but this Court has held that ERISA does not pre-empt "state-law mechanisms of executing judgments against" ERISA plans, *Mackey* v. *Lanier Collection Agency & Service, Inc.*, 486 U. S. 825, 831. Third, allowing pharmacies to decline to dispense a prescription if the PBM's reimbursement will be less than the pharmacy's cost of acquisition does not interfere with central matters of plan administration. The responsibility for offering the pharmacy a below-acquisition reimbursement lies first with the PBM. Finally, any "operational inefficiencies" caused by Act 900 are insufficient to trigger ERISA pre-emption, even if they cause plans to limit benefits or charge plan members higher rates. See *De Buono* v. *NYSA–ILA Medical and Clinical Services*

Syllabus

Fund, 520 U. S. 806, 816. Pp. 7–10.

891 F. 3d 1109, reversed and remanded.

SOTOMAYOR, J., delivered the opinion of the Court, in which all other Members joined, except BARRETT, J., who took no part in the consideration or decision of the case. THOMAS, J., filed a concurring opinion.

SUPREME COURT OF THE UNITED STATES

No. 18–540

LESLIE RUTLEDGE, ATTORNEY GENERAL OF ARKANSAS, PETITIONER *v.* PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

[December 10, 2020]

JUSTICE SOTOMAYOR delivered the opinion of the Court.

Arkansas' Act 900 regulates the price at which pharmacy benefit managers reimburse pharmacies for the cost of drugs covered by prescription-drug plans. The question presented in this case is whether the Employee Retirement Income Security Act of 1974 (ERISA), 88 Stat. 829, as amended, 29 U. S. C. §1001 *et seq.*, pre-empts Act 900. The Court holds that the Act has neither an impermissible connection with nor reference to ERISA and is therefore not pre-empted.

I

A

Pharmacy benefit managers (PBMs) are a little-known but important part of the process by which many Americans get their prescription drugs. Generally speaking, PBMs serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use. When a beneficiary of a prescription-drug plan goes to a pharmacy to fill

a prescription, the pharmacy checks with a PBM to determine that person's coverage and copayment information. After the beneficiary leaves with his or her prescription, the PBM reimburses the pharmacy for the prescription, less the amount of the beneficiary's copayment. The prescription-drug plan, in turn, reimburses the PBM.

The amount a PBM "reimburses" a pharmacy for a drug is not necessarily tied to how much the pharmacy paid to purchase that drug from a wholesaler. Instead, PBMs' contracts with pharmacies typically set reimbursement rates according to a list specifying the maximum allowable cost (MAC) for each drug. PBMs normally develop and administer their own unique MAC lists. Likewise, the amount that prescription-drug plans reimburse PBMs is a matter of contract between a given plan and a PBM. A PBM's reimbursement from a plan often differs from and exceeds a PBM's reimbursement to a pharmacy. That difference generates a profit for PBMs.

In 2015, Arkansas adopted Act 900 in response to concerns that the reimbursement rates set by PBMs were often too low to cover pharmacies' costs, and that many pharmacies, particularly rural and independent ones, were at risk of losing money and closing. 2015 Ark. Acts no. 900. In effect, Act 900 requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than that which the pharmacy paid to buy the drug from a wholesaler.

Act 900 accomplishes this result through three key enforcement mechanisms. First, the Act requires PBMs to tether reimbursement rates to pharmacies' acquisition costs by timely updating their MAC lists when drug wholesale prices increase. Ark. Code Ann. §17–92–507(c)(2) (Supp. 2019). Second, PBMs must provide administrative appeal procedures for pharmacies to challenge MAC reimbursement prices that are below the pharmacies' acquisition costs. §17–92–507(c)(4)(A)(i)(*b*). If a pharmacy could not have acquired the drug at a lower price from its typical

wholesaler, a PBM must increase its reimbursement rate to cover the pharmacy's acquisition cost. §17–92–507(c)(4)(C)(i)(*b*). PBMs must also allow pharmacies to "reverse and rebill" each reimbursement claim affected by the pharmacy's inability to procure the drug from its typical wholesaler at a price equal to or less than the MAC reimbursement price. §17–92–507(c)(4)(C)(iii). Third, and finally, the Act permits a pharmacy to decline to sell a drug to a beneficiary if the relevant PBM will reimburse the pharmacy at less than its acquisition cost. §17–92–507(e).

B

Respondent Pharmaceutical Care Management Association (PCMA) is a national trade association representing the 11 largest PBMs in the country. After the enactment of Act 900, PCMA filed suit in the Eastern District of Arkansas, alleging, as relevant here, that Act 900 is pre-empted by ERISA. See 29 U. S. C. §1144(a) (ERISA pre-empts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan").

Before the District Court issued its opinion in response to the parties' cross-motions for summary judgment, the Court of Appeals for the Eighth Circuit decided, in a different case, that ERISA pre-empts a similar Iowa statute. *Pharmaceutical Care Mgmt. Assn.* v. *Gerhart*, 852 F. 3d 722 (2017). The Eighth Circuit concluded that the Iowa statute was pre-empted for two reasons. First, it made "implicit reference" to ERISA by regulating PBMs that administer benefits for ERISA plans. *Id.,* at 729. Second, it was impermissibly "connected with" an ERISA plan because, by requiring an appeal process for pharmacies to challenge PBM reimbursement rates and restricting the sources from which PBMs could determine pricing, the law limited a plan administrator's ability to control the calculation of drug benefits. *Id.,* at 726, 731. Concluding that Arkansas' Act 900 contains similar features, the District Court held that

ERISA likewise pre-empts Act 900. 240 F. Supp. 3d 951, 958 (ED Ark. 2017). The Eighth Circuit affirmed. 891 F. 3d 1109, 1113 (2018). This Court granted certiorari. 589 U. S. ___ (2020).

II

ERISA pre-empts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U. S. C. §1144(a). "[A] state law relates to an ERISA plan if it has a connection with or reference to such a plan." *Egelhoff* v. *Egelhoff*, 532 U. S. 141, 147 (2001) (internal quotation marks omitted). Because Act 900 has neither of those impermissible relationships with an ERISA plan, ERISA does not pre-empt it.

A

To determine whether a state law has an "impermissible connection" with an ERISA plan, this Court considers ERISA's objectives "as a guide to the scope of the state law that Congress understood would survive." *California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N. A., Inc.*, 519 U. S. 316, 325 (1997) (internal quotation marks omitted). ERISA was enacted "to make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures." *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U. S. 312, 320–321 (2016). In pursuit of that goal, Congress sought "to ensure that plans and plan sponsors would be subject to a uniform body of benefits law," thereby "minimiz[ing] the administrative and financial burden of complying with conflicting directives" and ensuring that plans do not have to tailor substantive benefits to the particularities of multiple jurisdictions. *Ingersoll-Rand Co.* v. *McClendon*, 498 U. S. 133, 142 (1990).

ERISA is therefore primarily concerned with pre-empting laws that require providers to structure benefit

plans in particular ways, such as by requiring payment of specific benefits, *Shaw* v. *Delta Air Lines, Inc.*, 463 U. S. 85 (1983), or by binding plan administrators to specific rules for determining beneficiary status, *Egelhoff*, 532 U. S. 141. A state law may also be subject to pre-emption if "acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage." *Gobeille*, 577 U. S., at 320 (internal quotation marks omitted). As a shorthand for these considerations, this Court asks whether a state law "governs a central matter of plan administration or interferes with nationally uniform plan administration." *Ibid.* (internal quotation marks and ellipsis omitted). If it does, it is pre-empted.

Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law merely affects costs. In *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U. S. 645 (1995), this Court addressed a New York law that imposed surcharges of up to 13% on hospital billing rates for patients covered by insurers other than Blue Cross/Blue Shield (Blues). Plans that bought insurance from the Blues therefore paid less for New York hospital services than plans that did not. This Court presumed that the surcharges would be passed on to insurance buyers, including ERISA plans, which in turn would incentivize ERISA plans to choose the Blues over other alternatives in New York. *Id.,* at 659. Nevertheless, the Court held that such an "indirect economic influence" did not create an impermissible connection between the New York law and ERISA plans because it did not "bind plan administrators to any particular choice." *Ibid.* The law might "affect a plan's shopping decisions, but it [did] not affect the fact that any plan will shop for the best deal it can get." *Id.*, at 660. If a plan wished, it could still provide a uniform interstate benefit package. *Ibid.*

In short, ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage. *Id.,* at 668; cf. *De Buono* v. *NYSA–ILA Medical and Clinical Services Fund*, 520 U. S. 806, 816 (1997) (concluding that ERISA did not pre-empt a state tax on gross receipts for patient services that simply increased the cost of providing benefits); *Dillingham*, 519 U. S., at 332 (holding that ERISA did not pre-empt a California statute that incentivized, but did not require, plans to follow certain standards for apprenticeship programs).

The logic of *Travelers* decides this case. Like the New York surcharge law in *Travelers*, Act 900 is merely a form of cost regulation. It requires PBMs to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost. PBMs may well pass those increased costs on to plans, meaning that ERISA plans may pay more for prescription-drug benefits in Arkansas than in, say, Arizona. But "cost uniformity was almost certainly not an object of pre-emption." *Travelers*, 514 U. S., at 662. Nor is the effect of Act 900 so acute that it will effectively dictate plan choices. See *id.*, at 668. Indeed, Act 900 is less intrusive than the law at issue in *Travelers*, which created a compelling incentive for plans to buy insurance from the Blues instead of other insurers. Act 900, by contrast, applies equally to all PBMs and pharmacies in Arkansas. As a result, Act 900 does not have an impermissible connection with an ERISA plan.

B

Act 900 also does not "refer to" ERISA. A law refers to ERISA if it "'acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation.'" *Gobeille*, 577 U. S., at 319–320 (quoting *Dillingham*, 519 U. S., at 325; ellipsis omitted).

Act 900 does not act immediately and exclusively upon

ERISA plans because it applies to PBMs whether or not they manage an ERISA plan. Indeed, the Act does not directly regulate health benefit plans at all, ERISA or otherwise. It affects plans only insofar as PBMs may pass along higher pharmacy rates to plans with which they contract.

ERISA plans are likewise not essential to Act 900's operation. Act 900 defines a PBM as any "entity that administers or manages a pharmacy benefits plan or program," and it defines a "pharmacy benefits plan or program," in turn, as any "plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in [Arkansas]." Ark. Code Ann. §§17–92–507(a)(7), (9). Under those provisions, Act 900 regulates PBMs whether or not the plans they service fall within ERISA's coverage.[1] Act 900 is therefore analogous to the law in *Travelers*, which did not refer to ERISA plans because it imposed surcharges "regardless of whether the commercial coverage [was] ultimately secured by an ERISA plan, private purchase, or otherwise." 514 U. S., at 656; see also *Dillingham*, 519 U. S., at 328 (concluding that the relevant California law did not refer to ERISA plans because the apprenticeship programs it regulated did not need to be ERISA programs).

III

PCMA disagrees that Act 900 amounts to nothing more than cost regulation. It contends that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration. The mechanisms that PCMA identifies, however, do not require plan administrators to structure their benefit plans in any particular manner, nor

[1] PBMs contract with a variety of healthcare plans and programs that are not covered by ERISA, including Medicaid, Medicare, military, and market place plans.

do they lead to anything more than potential operational inefficiencies.[2]

PCMA first claims that Act 900 affects plan design by mandating a particular pricing methodology for pharmacy benefits. As PCMA reasons, while a plan might prefer that PBMs reimburse pharmacies using a MAC list constructed with an eye toward containing costs and ensuring predictability, Act 900 ignores that preference and instead requires PBMs to reimburse pharmacies based on acquisition costs. But that argument is just a long way of saying that Act 900 regulates reimbursement rates. Requiring PBMs to reimburse pharmacies at or above their acquisition costs does not require plans to provide any particular benefit to any particular beneficiary in any particular way. It simply establishes a floor for the cost of the benefits that plans choose to provide. The plans in *Travelers* might likewise have preferred that their insurers reimburse hospital services without paying an additional surcharge, but that did not transform New York's cost regulation into central plan administration.[3]

Act 900's appeal procedure likewise does not govern central matters of plan administration. True, plan administrators must "comply with a particular process, subject to state-specific deadlines, and [Act 900] dictates the substantive standard governing the resolution of [an] appeal." Brief for Respondent 24. Moreover, if a pharmacy wins its appeal, a plan, depending on the terms of its contract with a PBM, may need to recalculate and reprocess how much it

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[2] PCMA does not suggest that Act 900's enforcement mechanisms overlap with "fundamental components of ERISA's regulation of plan administration." *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U. S. 312, 323 (2016).

[3] PCMA also points to Act 900's requirement that PBMs update their MAC lists to reflect statutorily mandated prices. But that obligation does not affect plan design for the same reasons. Moreover, if PBMs were not required to update their MAC lists, they would be in constant noncompliance with Act 900's cost regulation.

(and its beneficiary) owes. But any contract dispute implicating the cost of a medical benefit would involve similar demands and could lead to similar results. Taken to its logical endpoint, PCMA's argument would pre-empt any suits under state law that could affect the price or provision of benefits. Yet this Court has held that ERISA does not pre-empt "state-law mechanisms of executing judgments against ERISA welfare benefit plans, even when those mechanisms prevent plan participants from receiving their benefits." *Mackey* v. *Lanier Collection Agency & Service, Inc.*, 486 U. S. 825, 831–832 (1988).

PCMA also argues that Act 900 interferes with central matters of plan administration by allowing pharmacies to decline to dispense a prescription if the PBM's reimbursement will be less than the pharmacy's cost of acquisition. PCMA contends that such a refusal effectively denies plan beneficiaries their benefits, but that argument misunderstands the statutory scheme. Act 900 requires PBMs to compensate pharmacies at or above their acquisition costs. When a pharmacy declines to dispense a prescription, the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement.

Finally, PCMA argues that Act 900's enforcement mechanisms interfere with nationally uniform plan administration by creating "operational inefficiencies." Brief for Respondent 34. But creating inefficiencies alone is not enough to trigger ERISA pre-emption. See, *e.g., Mackey*, 486 U. S., at 831 (holding that ERISA did not pre-empt a state garnishment procedure despite petitioners' contention that such actions would impose "substantial administrative burdens and costs" on plans). PCMA argues that those operational inefficiencies will lead to increased costs and, potentially, decreased benefits. ERISA does not pre-empt a state law that merely increases costs, however, even if plans decide to limit benefits or charge plan members higher rates as a result. See *De Buono*, 520 U. S., at 816 ("Any state tax,

or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted by the federal statute").

* * *

In sum, Act 900 amounts to cost regulation that does not bear an impermissible connection with or reference to ERISA. The judgment of the Eighth Circuit is therefore reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE BARRETT took no part in the consideration or decision of this case.

SUPREME COURT OF THE UNITED STATES

No. 18–540

LESLIE RUTLEDGE, ATTORNEY GENERAL OF ARKANSAS, PETITIONER *v.* PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

[December 10, 2020]

JUSTICE THOMAS, concurring.

I join the Court's opinion in full because it properly applies our precedents interpreting the pre-emptive effect of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U. S. C. §1144.

I write separately because I continue to doubt our ERISA pre-emption jurisprudence. *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U. S. 312, 327 (2016) (THOMAS, J., concurring). The plain text of ERISA suggests a two-part pre-emption test: (1) do any ERISA provisions govern the same matter as the state law at issue, and (2) does that state law have a meaningful relationship to ERISA plans? Only if the answers to both are in the affirmative does ERISA displace state law. But our precedents have veered from the text, transforming §1144 into a "vague and 'potentially boundless'. . . 'purposes and objectives' pre-emption" clause that relies on "generalized notions of congressional purposes." *Wyeth* v. *Levine*, 555 U. S. 555, 587 (2009) (THOMAS, J., concurring in judgment). Although that approach may allow courts to arrive at the correct result in individual cases, it offers little guidance or predictability. We should instead apply the law as written.

I

When construing a statutory provision, we begin with the text. *United States* v. *Alvarez-Sanchez*, 511 U. S. 350, 356 (1994). Section 1144(a) provides that certain of ERISA's provisions "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" with certain exceptions not relevant in this case.

The term "supersede" precludes reading the statute as categorically pre-empting any state law related to employee benefit plans. Rather, it suggests a replacement or substitution instead of a blanket pre-emption. See Webster's Third New International Dictionary 2295 (1976) (defining "supersede" to mean, among other things, "to take the place of and outmode by superiority"); *District of Columbia* v. *Greater Washington Bd. of Trade*, 506 U. S. 125, 135–136 (1992) (Stevens, J., dissenting) (noting the word "supersede" is "often overlooked").

Where Congress seeks to pre-empt state laws *without* replacing them, it typically uses different words. See, *e.g.,* 84 Stat. 88, codified in 15 U. S. C. §1334(b) (stating in a "preemption" section that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act"); 49 U. S. C. §41713(b)(1) ("[A] State . . . may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier"). Congress knows how to write sweeping pre-emption statutes. But it did not do so here. Applying the statutory text, the first step is to ask whether a provision in ERISA governs the same matter as the disputed state law, and thus could replace it.

The next step is to determine whether the state law "relate[s] to" employee benefit plans. 29 U. S. C. §1144(a). The Court has expressed concern that a *literal* reading of

this phrase is so broad that it is meaningless. See *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U. S. 645, 655 (1995). But many times it is the ordinary, not literalist, meaning that is the better one. See, *e.g., McBoyle* v. *United States*, 283 U. S. 25, 26 (1931) ("vehicle" in the 1930s did not include aircraft because "in everyday speech 'vehicle' calls up the picture of a thing moving on land"). "[A] reasonable person conversant with applicable social conventions" would not understand "relate to" as covering any state law with a connection to employee benefit plans, no matter how remote the connection. Manning, What Divides Textualists From Purposivists? 106 Colum. L. Rev. 70, 77 (2006); see also *California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N. A., Inc.*, 519 U. S. 316, 336 (1997) (Scalia J., concurring) (interpreting "relate to" literally would lead to results "no sensible person could have intended"). If someone, for instance, asserted that he is "related to Joe," it would be reasonable to presume a close familial relationship. No one would assume that the speaker was referencing a mutual tie to Adam and Eve. So too here. A state law needs more than a "tenuous, remote, or peripheral" connection with ERISA plans to trigger the statute. *Shaw* v. *Delta Air Lines, Inc.*, 463 U. S. 85, 100, n. 21 (1983); cf. *Wisconsin Dept. of Revenue* v. *William Wrigley, Jr., Co.*, 505 U. S. 214, 231 (1992) ("'the law cares not for trifles'").

II

Here, the parties have not pointed to any ERISA provision that governs the same matter as Act 900. That alone should resolve the case. But the parties certainly cannot be faulted for not raising this argument. Our amorphous precedents have largely ignored this step. *E.g., District of Columbia*, 506 U. S., at 129.

Instead, we have asked only if the state law "'relate[d] to'" ERISA plans. *Ibid.* But this has proved problematic

because of "how much state law §1144 would pre-empt if read literally." *Gobeille*, 577 U. S., at 328 (THOMAS, J., concurring). Instead of reverting to the text, however, we decided that "relate to" is so "indetermina[te]" that it cannot "give us much help drawing the line." *Travelers*, 514 U. S., at 655.

Having paid little attention to the actual statutory test, we crafted our own, asking whether the challenged state law frustrates the "'objectives'" of ERISA. *Gobeille*, 577 U. S., at 320. Under this approach, the Court will declare as pre-empted "state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law." *Wyeth*, 555 U. S., at 583 (opinion of THOMAS, J.). Our case law states that under an objectives and purposes pre-emption approach, a state law is pre-empted if it has a "reference to" or an "impermissible connection with" ERISA plans. *Gobeille*, 577 U. S., at 319–320. But this vague test offered "no more help than" the "'relate to'" one. *Travelers*, 514 U. S., at 656.

Our more recent efforts to further narrow the test have just yielded more confusion. A state law references ERISA only if it "'acts immediately and exclusively upon ERISA plans. . . or where the existence of ERISA plans is essential to the law's operation.'" *Gobeille*, 577 U. S., at 319–320 (ellipsis in original). A connection with ERISA plans is impermissible only if it "'governs. . . a central matter of plan administration'" or "'interferes with nationally uniform plan administration.'" *Id.*, at 320. (ellipsis in original).[1] Alt-

[1] We have also held that a state law might have an impermissible connection with ERISA plans if the indirect economic effects of the state law "force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U. S. 645, 668 (1995).

hough, at first blush, that may seem more precise than asking if a law "relates to" ERISA, it has proven just as difficult to apply consistently, leading many members of the Court to suggest still other methods. See, *e.g.*, *Egelhoff* v. *Egelhoff*, 532 U. S. 141, 152 (2001) (Scalia, J., concurring); *Aetna Health Inc.* v. *Davila*, 542 U. S. 200, 222–224 (2004) (Ginsburg, J., concurring). Instead of relying on this "accordion-like" test that seems to expand or contract depending on the year, Reece, The Accordion Type Jurisprudence of ERISA Preemption Creates Unnecessary Uncertainty, 88 UMKC L. Rev. 115, 124, n. 71 (2019), perhaps we should just interpret the text as written.

III

Stare decisis concerns need not caution against a return to the text because the outcomes of our recent cases—if not the reasoning— are generally consistent with a text-based approach. Indeed, since *Travelers* every state law this Court has held pre-empted involved a matter explicitly addressed by ERISA provisions. See, *e.g.*, *Boggs* v. *Boggs*, 520 U. S. 833, 843–854 (1997) (pre-empting state law and discussing ERISA provisions with which it conflicts); *Aetna Health*, 542 U. S., at 204 (holding that states cannot create new causes of action that conflict with ERISA's "'interlocking, interrelated, and interdependent remedial scheme,'" located in §502(a) of ERISA).[2]

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[2] The Court has found something to be "a central matter of plan administration" only when the matter is addressed by ERISA's text. *E.g.*, *Egelhoff* v. *Egelhoff*, 532 U. S. 141, 148 (2001); *Gobeille* v. *Liberty Mut. Ins. Co.*, 577 U. S., at 321–322. And if the state law interferes with national uniformity but ERISA does not address the matter, we have held that the matter in question does not require uniformity. *Travelers*, 514 U. S., at 662; *ante*, at 5, ("not every state law that. . . causes some disuniformity in plan administration" is pre-empted). We have also held that ERISA does not pre-empt state laws regulating ERISA plans engaging in activity not regulated by ERISA, like running a hospital. See *De Buono* v. *NYSA–ILA Medical and Clinical Services Fund*, 520 U. S. 806

But it is not enough for this Court to reach the right conclusions. We should do so in the way Congress instructed. Indeed, although we have generally arrived at the conclusions we would arrive at under a text-based approach, our capacious, nontextual test encourages departure from the text. The decision below is testament to that problem. We unanimously reverse that decision today, but we can hardly fault judges when they apply the amorphous test that we gave them. We can and should do better.

(1997). That makes sense because ERISA has nothing to say about those activities.

LACK OF FISCAL IMPACT AND POTENTIAL ECONOMIC BENEFIT OF PUBLIC LAW NO. 82 OF 2019 REGULATING PHARMACY BENEFIT MANAGERS (PBMS) AND PHARMACY BENEFIT ADMINISTRATORS (PBAS).

Submitted to:

Hon. Wanda Vázquez Garced, Governor

Via
Edna I. Díaz de Jesús, BHE, MPA, Patient's Advocate

By Juan Lara, PhD
Economist and Partner, Advantage Business Consulting

February 19, 2020

The FOMB requested from Governor Wanda Vázquez a certification of Public Law No. 82 of 2019 as being in compliance with the certified Fiscal Plan and Budget. The purpose of this memorandum is to inform the Governor and the FOMB about the potential fiscal impact of the law. In this regard, the points to be argued and documented are:

1. That the law has no fiscal impact that could render it objectionable in light of the Fiscal Plan and Budget.
2. That a positive fiscal impact may be expected from the law due to the collection of licensing and audit fees, and, mostly, from the potential savings to the government health plan (the GHP) as a client of PBMs.
3. That the law embodies measures to promote the healthy management and oversight of government funds, which is in line with the objectives and directives of the FOMB.

Law 82 was enacted to regulate Pharmacy Benefit Managers (PBMs) and Pharmacy Benefit Administrators (PBAs) in Puerto Rico. In so doing, Puerto Rico joined more than 39 US states that have enacted legislation to regulate these entities, which act as intermediaries between manufacturers of medications and third-party payers for drugs dispensed in pharmacies, such as health insurance plans, corporations and local governments.

The purpose of state regulation is to ensure transparency and prevent business practices that have been shown in several cases to inflate the cost and/or limit the availability of medications to the detriment of health insurance providers—public and private—and end users (patients). These problems may, and sometimes do, arise when the unchecked exercise of the role of

intermediary allows a PBM to withhold information on costs and prices from the parties at the ends of the intermediation chain.

There is ample evidence of states and other payers for health insurance realizing substantial savings through the regulation or elimination of PBMs, as illustrated later in this memorandum. Law 82 does not seek to eliminate PBMs, but rather to mandate transparency in their operations to prevent excessive charges to the GHP and private insurers in Puerto Rico that end up as higher costs to patients, and to ensure the availability of medications to all patients.

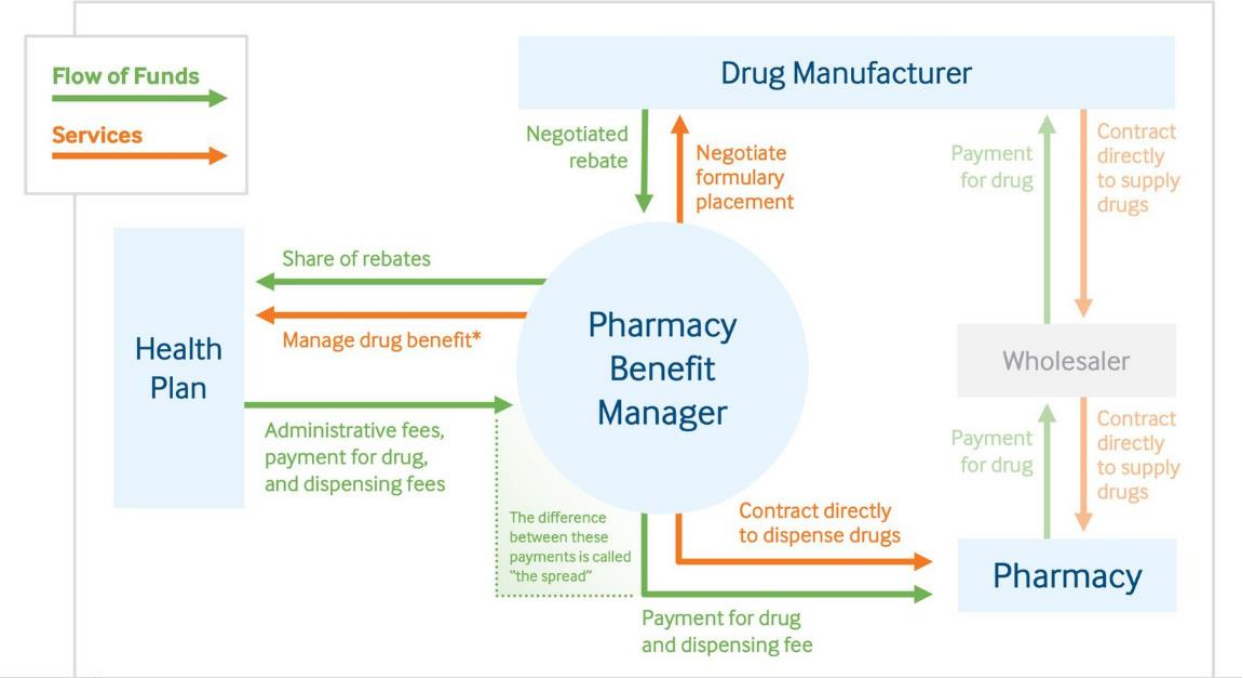
The cost and availability of medications is a matter of public interest, especially in Puerto Rico, where the government pays for the health insurance benefits of a large portion of the population. States such as Ohio have carried out audits of some PBMs and concluded that publicly funded health insurance had been overbilled to the tune of millions of dollars as a result of non-transparent pricing schemes. Hence the wave of regulatory legislation across states in recent years.

The following diagram from The Commonwealth Fund illustrates the nature and operation of PBMs and helps to understand the potential for cost-raising practices when prices, rebates and other data are not transparent to stakeholders in the intermediation process, including the government.

PBMs are supposed to negotiate discounts and rebates from manufacturers and to share those savings with health insurance plans and governments, as in the case of the GHP. On the other side of the intermediation chain, PBMs are supposed to pay pharmacies a dispensing fee and the agreed-upon cost of medications dispensed to end users.

Exhibit 1

Role of a Pharmacy Benefit Manager in Providing Services and Flow of Funds for Prescription Drugs



Experience in many jurisdictions has shown that lack of transparency often leads to PBMs overcharging health plans and undercompensating pharmacies, thus extracting an excessive profit. Such an outcome is contrary to the purpose of the PBM, which is to generate savings in the cost of medications to health insurers and to improve the overall economic efficiency of the flow of medications from manufacturers to end users.

In the administration of pharmacy benefits in health insurance plans, PBMs also often have the power to not authorize the use of a particular medication or to impose authorization procedures that may cause long delays in a patient's access to prescribed medication. This causes additional costs to health insurance plans and the GHP when patients missing their

medication seek treatment in hospitals or emergency rooms, circumventing the more cost-effective primary care provided by the plan.

The enactment and enforcement of Law 82 is a necessary public policy action that is expected to have a positive fiscal impact through the GHP and to improve the overall economic efficiency of the dispensing of prescription medications in Puerto Rico. This conclusion follows from several facts:

- The law does not create an administrative burden that might increase government expenditures, since the regulatory office will operate with the personnel and structure of SARAF and the Department of Health. SARAF personnel are experienced and knowledgeable in the matters involved in the regulatory process, since they currently oversee the medication chain in the jurisdiction of Puerto Rico.
- The law provides for transparency and audits that may result in large savings to the GHP, which spends about $800 million per year in medications and pays over $30 million annually in fees to PBMs.
- The law provides a tool to audit rebates negotiated by PBMs contracting to the GHP and to ensure that savings flow wholly or in part to the GHP and help to offer more and better benefits to patients.
- The law empowers a Regulating Commissioner to regulate practices that may result in excessive price spreads in the operation of PBMs contracting to the GHP and private health plans.

- The law empowers a Regulating Commissioner to regulate practices that may impose financial strain on pharmacies, thus protecting the efficiency of the drug-dispensing industry.
- The law empowers a Regulating Commissioner to regulate practices that may impose undue delays in the dispensing of medications, thus causing cost pressures through deteriorating health outcomes.

No Negative Budget Impact

Regarding point #1 in the introduction above, the FOMB is hereby informed that the law will have a zero or negligible impact on government spending (hence, on the Budget). The law does not create a new administrative structure, but rather places the Office of the Regulating Commissioner within the existing structure of the Department of Health and requires the Commissioner to be appointed by the Secretary of Health from the ranks of the Department's qualified officials. In addition, the regulatory office will operate with support from SARAF staff. The costs of audits will be paid by the audited companies, as with all entities regulated by the Department of Health, resulting in no cost to the government. In addition, the law authorizes the Commissioner to request expert advice, when needed, from resources in the Department of Health and the Office of the Commissioner of Insurance.

Law 82 also gives the Patient's Advocate the authority to evaluate and adjudicate patients' complaints against PBMs. The lack of such authority, prior to the enactment of Law 82, constituted a regulatory omission that hindered the Advocate's operation. Claims against PBMs

will be handled by the existing personnel and resources of the Patient's Advocate office, with no additional cost to the government.

Potential Positive Revenue Impact

The law requires PBMs and PBAs to obtain a license from the Office of the Regulating Commissioner and to pay a licensing fee of $20,000. There are currently nine (9) PMBs and PBAs operating in Puerto Rico. Under Law 82, these entities will generate at least $180,000 in annual fees that will help to defray the operating costs of the Office, thus causing a positive revenue impact.

An additional revenue effect is the collection of auditing fees from the entities as they are subjected to regular audits by the Office of the Regulating Commissioner. Entities may also be fined on occasion if found in violation of Law 82 and related regulations. Fines will also have a positive revenue impact. Prior to the enactment of Law 82, any deficiencies or violations in the operations of PBMs and PBAs were without consequence to the entities themselves, although damaging to others.

The largest potential revenue impact could result from savings to the GHP due to a reduction in the cost of medications and medical expenses. There might also be savings for private health insurers and end users (patients), which is an important part of the rationale for the legislative action to regulate this industry. However, the private benefits, while potentially quite important, have no direct bearing on the assessment of the fiscal impact of Law 82.

According to the Medicaid and CHIP Payment and Access Commission (MACPAC), the GHP had 1.5 million enrollees in 2017 (47% of the population), of which 1.3 million were covered by Medicaid. MACPAC projects that the GHP will spend $808.6 million in medications in 2020, or 29% of a total budget of $2,789 million. According to industry sources, the GHP pays for 11 million prescriptions each year, out of a total of 67 million prescriptions served annually on the island.

In the certified fiscal plan for the Commonwealth of Puerto Rico, the FOMB calls for reductions in GHP payment for medications as part of the effort to "bend the curve" of premium inflation resulting from rising health care costs. This guideline falls under the Board's broader goal of implementing good management measures that help control or reduce the expenditure of public funds. There cannot be reasonable control and measurement of costs to the government without regulation encompassing the entire chain of medication delivery. By leaving a key link in the chain unregulated, prior to Law 82, Puerto Rico's lawmakers risked missing one of the major goals of the FOMB and the fiscal plan. According to the plan, "ASES can lower the cost of prescription drug coverage by replacing higher cost drugs with cheaper, equally effective alternatives, driving increased use of generics and imposing utilization controls." Law 82 is designed to help control the costs of drugs to health insurance plans and end users, among other objectives, thus pointing in the same direction as the FOMB's guidelines.

The fiscal plan also calls for rationalizing the use of emergency room facilities as a way of reducing costs in the GHP. According to the fiscal plan, Puerto Ricans use emergency room services three times as much as their mainland counterparts, with about 90% of visits to the

emergency room being for non-emergencies. The legislative record shows that in the hearings for Law 82 a number of patient rights organizations testified that the practice by PBMs of delaying authorization for prescription medications often results in patients seeking treatment and medication in hospital emergency rooms. A three-month delay in authorizing a medication is common with PBMs, according to patient rights organizations, and delays of five to six months have also been documented in cancer patients. Delays are especially critical for patients with severe conditions, such as delaying chemotherapy drugs between sessions, which leads to a loss of efficiency in a type of therapy that is meant to have a cumulative effect. Law 82 requires PBMs to make a decision on the authorization of prescribed medications in a period no longer than 24 hours, which may be extended to 72 hours in some cases.

A key principle of the GHP is the emphasis on primary care and prevention. Better health of patients means lower costs for the plan. Prevention is a low-cost approach to good health outcomes. In turn, timely medication is essential in preventive care and reducing associated costs.

The withholding of medication for the sake of profit optimization by a PBM is not only inhumane, but also cost-ineffective for the GHP, because it ends up producing greater use of emergency room and hospitalization services by patients whose health is compromised by lack of timely access to proper therapy. Delaying access to medication may also lead to the emergence of additional health conditions that increase the cost of treatment and cause greater outlays by the GHP. In the legislative record, patient rights organizations denounced cases of leukemia patients that had to interrupt chemotherapy because of authorization delays.

As shown by several stateside experiences, auditing PBMs could be a significant source of revenues to the GHP from recovery of amounts overpaid for services. The sheer volume of the GHP's payments for medications (around $800 million) suggests a significant potential for gains from audits and makes it advisable to investigate cost calculations and price-setting practices by the PBMs under contract to the plan. According to the National Coalition of State Legislatures (NCSL), the Ohio state attorney filed a lawsuit against one PBM to recover $16 million in overpayments following a 2018 audit. NCSL also reports that West Virginia has saved an estimated $38 million per year since abolishing all Medicaid CMO contracts with PBMs in 2017.

The National Community Pharmacists Association (NCPA) has researched the impact of regulating PBMs in various states and found evidence of large savings. The following table presents a sample of the savings documented by NCPA researchers, some of which are one-time recoups while others are recurring benefits.

State or Entity	Action	Actual or Anticipated Savings
South Dakota	Transparency Measures	$820,000 annually
Arkansas	Auditing, Transparent RFP, reduced pharmacy charges	$13,000,000
Wisconsin	Moved to a Transparent PBM	$1,500,000
University of Michigan	Cancelled five PBM contracts and enacted regulations	$8,600,000 annually
New Jersey	Moved to a Transparent PBM	$540,000,000
Illinois	Direct negotiation of pharmacy benefits	$10,000,000 annually
Texas	Enacted Transparent Contract	$265,000,000
Tricare (Serving Armed Services personnel and dependents)	Negotiates prices directly, not through PBM	$1.687 billion
West Virginia	Abolished Medicaid CMO contracts with PBMs	$38,000,000 annually

Another matter that warrants investigation as a potential source of revenues is the negotiation of rebates from manufacturers. The GHP contracts with a PBM to operate its pharmacy rebate program, which generated $225.5 million in 2018. Such rebates are supposed to be kept in whole by the GHP, net of administration costs, and it is good public policy to investigate if PBMs are managing this program in the best interest of the GHP, maximizing the potential benefit to the local government. Law 82 provides for regular audits in this area, which could result in additional revenues from rebates.

Since a substantial portion of the GHP's expenditures are covered with federal funds, federal authorities conduct reviews of Puerto Rico's Medicaid program integrity. The 2012 review by the Centers for Medicare and Medicaid Services (CMS) identified a number or regulatory compliance issues involving the PBMs under contract to GHP, such as:

- Not capturing all required ownership, control and relationship information of PBMs.
- Not including in contracts with PBMs the requirement to disclose, upon request, specified business transaction information.
- Not capturing all required health care-related criminal conviction disclosure information from PBMs.
- Not complying with the State Plan requirement to review PBMs' policies and employee handbooks pertaining to the False Claims Act.

Such findings, which resulted in the requirement of a corrective action plan by CMS, illustrate the need to strengthen the GHP's oversight and audit capabilities, which is a main objective of Law 82.

The GHP pays about $30 million annually to two PBMs. In a letter to ASES, the government agency in charge of the GHP, dated June 29, 2018, the FOMB alerted that contracts with the two PBMs had "not been competitively sourced since 2006, which could be indicative of a procurement approach that is inconsistent with principles outlined in the Fiscal Plan." Lack of competition in awarding PBM contracts is a cause for concern and yet another reason to demand regular auditing of PBMs providing services to the GHP.

Practices to be prevented by Law 82

As mentioned in the introductory paragraphs above, PBMs have been found to engage in business practices that can result, and do result, in unjustifiably high prices for medications. Insurance providers, pharmacies and patients are impacted by these pricing practices to varying degrees, as has been documented in studies and cases reported by NCSL.

The problem arises primarily from lack of transparency in the pricing practices of PBMs; which state regulation on the mainland, and now in Puerto Rico, seeks to redress. The intermediation by PBMs between drug manufacturers, insurance providers, pharmacies and end users, is subject to asymmetric information when such intermediation proceeds without regulatory oversight. The asymmetry in the availability of information to the various players in the process takes away from the efficiency that market-based mechanisms are expected to deliver.

The NCSL has compiled a record of actions by state legislatures to enforce transparency in the operation of PBMs and PBAs (especially the former). These actions have focused on a number

of practices that have been found to be particularly suspect and/or harmful. Puerto Rico cannot stay behind. Some of these are listed and briefly explained below.

Gag Clauses

A gag clause in a contract between a PBM and contracting pharmacy prohibits the pharmacy from telling customers that they may save money on a medication by paying out-of-pocket instead of through insurance. This is patently contrary to transparency in the pricing process, and directly hurts end users, but also insurers who end up paying for a drug that the patient might have preferred to pay out-of-pocket. According to NCSL, thirty-three (33) states have already outlawed gag clauses.

Spread Pricing

Spread pricing occurs when a PBM is compensated by keeping the difference between the price it charges a health insurance provider and the price it reimburses to pharmacies. When the parties at the ends of the intermediation process don't have access to information about price spreads, such spreads may become excessive, resulting in inflated profits for the PBM at the expense of insurers and pharmacies. According to NCSL, a 2018 audit of Ohio's Medicaid MCOs uncovered that PBMs charged the state a 31% spread for generic drugs that comprised more than 86% of all prescriptions.

Pharmacy Audits

PBMs audit pharmacies to prevent fraud and validate prescription data. This is a reasonable and necessary practice. However, state legislatures have intervened to address complaints by

pharmacies of unfair auditing practices that result in stiff fines and penalties. According to NCSL, several states have legislated to set fair auditing standards for PBMs.

Co-pay Clawbacks

An extreme example of market failure due to asymmetric information is the co-pay clawback. This happens when the copayment exacted from the end user is higher than the total cost of the medication to the insurer and the PBM. As described by the NCSL, this practice usually goes hand-in-hand with a gag clause, which prohibits the pharmacy from warning the end user. It is hard to think of a practice more deserving of strict regulation than the co-pay clawback.

Regulatory Response

The unfair practices described above have led many states to investigate the operations of PBMs and enact preventive and/or corrective legislation.

The prevention of these practices in Puerto Rico through sensible and cost-effective regulation of PBMs may have a significant revenue impact through savings for the GHP (and also a healthy cost-reducing effect in the private health-insurance market). In fact, it is advisable to instruct the GHP (i.e. ASES) to carry out an audit of PBMs and PBAs contracting with the agency, to ensure that contracting entities are not engaging in the wrongful practices described above.

The regulation and oversight mandated by Law 82 is a necessary instrument to avoid the emergence of these cost-raising practices in Puerto Rico's PBMs, and especially to protect the

GHP from overpayment for medications. Even more important is that the law protects patients from unfair practices and guarantees access to appropriate and timely medication that saves lives.

In economic theory, government regulation of private market activities is justifiable and recommended when it corrects market failure that harms consumers or other parties, and when the public interest is at stake. Both criteria apply to the regulation embodied in Law 82. By improving transparency and providing for auditing and enforcement, the law will remove any incentives that may currently exist for PBMs and PBAs to engage in cost-raising practices.

Needless to say, regulation must also be justifiable in terms of cost-effectiveness. Law 82 also meets this criterion, as the administrative support for the regulation is of minimal incremental cost to the Department of Health and the government of Puerto Rico. In sum, the law is a cost-effective tool to protect the island's population and the GHP from unnecessary expense and to facilitate access to medications by those who need it most.

Conclusion

Law 82 does not entail any incremental costs to Puerto Rico's government and will likely produce savings and additional revenues for the GHP. The law is a cost-effective and fiscally responsible instrument to better discharge the government's responsibility to protect citizens in a matter of overriding public interest.